

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

DAVID CHRISTENSON
5754 Clevendon Lane
Oshkosh, WI 54904,

ANNIKEN PROSSER
W2973 Farmstead Drive
Appleton, WI 54915,

Plaintiffs,

v.

Case No. 20-cv-194

ALEX AZAR, in his capacity as Secretary
of the United States Department of Health
and Human Services,
200 Independence Avenue, S.W.
Washington, DC 20201,

Defendant.

COMPLAINT

Plaintiffs DAVID CHRISTENSON and ANNIKEN PROSSER (collectively, “Plaintiffs”), by their undersigned counsel, bring this action against Defendant Alex Azar, in his official capacity as Secretary of the United States Department of Health and Human Services (hereinafter, “the Secretary”), to obtain declaratory and injunctive relief for violations of federal law. Plaintiffs make the following allegations based on the investigation of counsel, information and belief, and on personal knowledge:

I. SUMMARY

1. Tragically, each of the two Plaintiffs is suffering from a particularly deadly form of brain cancer, glioblastoma multiforme (GBM), and they are seeking coverage for life-saving treatment. In a particularly cruel twist, the Secretary is forcing Plaintiffs to prove that they are entitled to the same treatment on a monthly basis, and then the Secretary’s decisions differ from

month to month with no predictable pattern. The Secretary is playing a game of chance with the Plaintiffs' lives: maybe this month they will get life-saving treatment or maybe they won't.

2. The main issue in this case is whether collateral estoppel prevents the Secretary from re-litigating issues already lost in administrative proceedings involving the same parties?

3. The Secretary has asserted that his regulations preclude collateral estoppel and that month-to-month differing decisions on Plaintiffs' life-saving care are not arbitrary and capricious even though the facts and/or circumstances have not changed. These positions are wholly without merit under well-established issue preclusion law. *U.S. v. Stauffer Chemical Co.*, 464 U.S. 165 (1984); *Astoria Federal Savings & Loan v. Solimino*, 501 U.S. 104 (1991)

4. The other issue is whether it is arbitrary and capricious under basic principles of administrative law for the Secretary to issue conflicting decisions when the facts and/or circumstances have not changed and where the Secretary has determined multiple times that coverage of a medical device to treat Plaintiffs' brain cancer was appropriate

II. JURISDICTION

5. This Court has jurisdiction over this action pursuant to 42 U.S.C. §§ 405(g) and 1395ff. Each of the Plaintiffs is filing suit after final decisions of the Medicare Appeals Council (acting on behalf of the Secretary) denying coverage of their Medicare claims (and, therefore, have exhausted their administrative remedies), the amount-in-controversy is more than \$1,630 (42 U.S.C. §§ 1395ff(b)(1)(E)(i) and 1395ff(b)(1)(E)(iii)), and this suit was filed within 60 days of the Secretary's final decisions, as a result of escalation. See 42 C.F.R. § 405.1016(f).

6. Venue is proper in this district pursuant to 42 U.S.C. § 405(g) because this action is being brought in the district of Plaintiffs' residence.

III. PARTIES

7. Plaintiff David Christenson is an individual and a resident of the State of Wisconsin. Mr. Christenson is eligible for Medicare on the basis of age or disability as previously determined by the Secretary.

8. Plaintiff Anniken Prosser is an individual and a resident of the State of Wisconsin. Ms. Prosser is eligible for Medicare on the basis of age or disability as previously determined by the Secretary.

9. Defendant Alex Azar is sued in his official capacity as the Secretary of Health and Human Services.

IV. LEGAL BACKGROUND

10. The doctrine of mutual collateral estoppel applies to the government and may bar the government from re-litigating facts/issues the government previously litigated and lost. *See U.S. v. Stauffer Chemical Co.*, 464 U.S. 165 (1984).

11. Moreover, collateral estoppel may be based not only on litigation in federal or state courts but also on proceedings before an agency, when the agency is acting in a judicial capacity. In *Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991), the Supreme Court held that:

We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves dispute issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court

has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

12. Numerous courts have applied collateral estoppel to Federal agency decisions.

Manitowoc Cranes LLC v. Sany America Inc., 2017 WL 6327551, *2 (E.D. Wis. 2017), *citing B & B Hardware, Inc. v. Hargis Indus., Inc.*, 135 S.Ct. 1293, 1303 (2015); *see, e.g., Brewster v. Barnhart*, 145 Fed.App'x. 542 (6th Cir. 2005) (SSA ALJ bound by prior determination).

V. FACTUAL BACKGROUND

Tumor Treatment Field Therapy (TTFT)

13. Glioblastoma multiforme (GBM) is an unusually deadly type of brain cancer. Without treatment, survival is typically three months. With traditional treatment, the survival rate at two years after treatment is ~31%, while at five years, only ~5% of patients are living.

14. More recently, a process for treating GBM using alternating electric fields has been developed. This is known as tumor treatment field therapy (TTFT). Alternating electric fields interfere with tumor cell replication and have been shown to dramatically increase the period during which the GBM does not progress, as well as overall survival rates.

15. In ground-breaking papers published in the Journal of the American Medical Association (JAMA) in 2015 and 2017, TTFT was shown to increase the two-year survival rate by more than 38% and to nearly triple the five-year survival rate.¹

16. TTFT was the first significant advance in treating GBM in more than a decade. TTFT has become the standard of care for treating GBM and essentially all private insurers

¹ See Stupp, et al., "MAINTENANCE THERAPY WITH TUMOR-TREATING FIELDS PLUS TEMOZOLOMIDE VS. TEMOZOLOMIDE ALONE FOR GLIOBLASTOMA: A RANDOMIZED CLINICAL TRIAL", JAMA, Vol. 314, No. 23, pgs. 2535-43 (December 15, 2015); Stupp, et al., "EFFECT OF TUMOR TREATING FIELDS PLUS MAINTENANCE TEMOZOLOMIDE VS. MAINTENANCE TEMOZOLOMIDE ALONE ON SURVIVAL IN PATIENTS WITH GLIOBLASTOMA", JAMA, Vol. 318, No. 23, pgs. 2306-2316 (December 19, 2017).

cover TTFT. It saves and/or extends GBM patients' lives, in some instances, by years. Between January 2016 and December 2018, at least 93 scientific papers were published demonstrating the effectiveness of TTFT. It is given a level one recommendation in the National Comprehensive Cancer Network (NCCN) guidelines, *i.e.*, there is consensus, among the experts, based on a high level of evidence, that TTFT is a recommended intervention.

17. The sole supplier of the equipment that delivers Tumor Treatment Field Therapy Novocure, Inc. which manufactures the Optune system. The Optune TTFT system is rented on a monthly basis. Thus, after a patient is prescribed the Optune system, they will have separate monthly claims for Medicare coverage.

18. Sadly, there is no known cure for GBM and patients prescribed TTFT treatment must continue that treatment for the rest of their hopefully extended lives.

The Medicare Appeals Process

19. Plaintiffs are enrolled in the medical benefit commonly known as "Original Medicare." Claims submitted by beneficiaries are subject to a five (5) level appeal process, that can (and typically does) take more than a year. At the first stage, a beneficiary submits a claim. If the claim is denied, the beneficiary can request "redetermination." If the claim is still denied, the beneficiary can request "reconsideration." If the claim is still denied, the beneficiary can appeal to an Administrative Law Judge (ALJ). If the ALJ denies the claim, the beneficiary can appeal to the Medicare Appeals Council (MAC). Finally, if the claim is still denied, the beneficiary can file suit in district court.

20. While the statutes and regulations require both ALJs and the MAC to issue decisions within 90 days, those deadlines are routinely missed. Thus, beneficiaries seeking

coverage are often thrown into a multi-year effort to obtain final decisions in their cases before they can seek relief in a federal court.

a. Facts Specific to Mr. Christenson

21. Plaintiff David Christenson has been diagnosed with a GBM and, after receiving other treatment, has been prescribed TTFT.

22. Mr. Christenson has previously received three favorable decisions from ALJs which determined that TTFT is medically reasonable and necessary for him and is a covered benefit. ALJ Appeal Nos. 1-8285652321 (April 2, 2019), 1-8416229632 (June 6, 2019), and 1-8637714249 (September 11, 2019). The Secretary did not appeal any of those decisions and they have become final.

23. Despite the prior favorable rulings, ALJ Watson issued a decision on September 12, 2019 in ALJ Appeal No. 1-8630709341 holding that TTFT is not medically reasonable and necessary for Mr. Christenson and, therefore, denying coverage.

24. Mr. Christenson timely appealed ALJ Watson's decision on September 18, 2019. When no decision was received within 90 days, Mr. Christenson filed a notice of escalation pursuant to 42 C.F.R. § 405.1016(f) on January 3, 2020.

25. On January 22, 2020, the Medicare Appeals Council (MAC) responded indicating that they could not timely issue a decision and that judicial review was authorized within 60 days of the letter.

26. Accordingly, Mr. Christenson is entitled to judicial review.

b. Facts Specific to Ms. Prosser

27. Plaintiff Anniken Prosser has been diagnosed with a GBM and, after receiving other treatment, has been prescribed TTFT.

28. Ms. Prosser has previously received a favorable ALJ decision determining that TTFT is medically reasonable and necessary for her and is a covered benefit. ALJ Appeal No. 1-8416188648. The Secretary did not appeal that decision and it has become final.

29. Despite the prior favorable, ALJ Grow issued a decision on June 19, 2019 in ALJ Appeal No. 1-8390277469 holding that TTFT is not medically reasonable and necessary for Ms. Prosser and, therefore, denying coverage.

30. Ms. Prosser timely appealed ALJ Grow's decision on July 12, 2019. When no decision was received within 90 days, Ms. Prosser filed a notice of escalation on January 2, 2020 pursuant to 42 C.F.R. § 405.1016(f). No response has been received to date.

31. On January 22, 2020, the Medicare Appeals Council (MAC) responded indicating that they could not timely issue a decision and that judicial review was authorized within 60 days of the letter.

32. Accordingly, Ms. Prosser is entitled to judicial review.

VI. LEGAL CAUSES OF ACTION

COUNT I **Violation of 42 U.S.C. §405(g)** (contrary to law)

33. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as contrary to law, as arbitrary and capricious, an abuse of discretion, and unsupported by the evidence, and issue an order finding that Plaintiffs' claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT II **Violation of 5 U.S.C. § 706(1)** (unlawfully withheld or unreasonably delayed)

34. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as unlawfully withheld or unreasonably delayed and unsupported by the evidence, and

issue an order finding that Plaintiffs' claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT III

Violation of 5 U.S.C § 706(2)(A)

(arbitrary and capricious, abuse of discretion, not in accordance with law)

35. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law, and issue an order finding that Plaintiffs' claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT IV

Violation of 5 U.S.C § 706(2)(C)

(in excess of statutory jurisdiction, authority, or limitations or short of statutory right)

36. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as in excess of the Secretary's authority and limitations and short of Plaintiffs' statutory rights and issue an order finding that Plaintiffs' claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT V

Violation of 5 U.S.C § 706(2)(D)

(without observance of procedure required by law)

37. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as done without observance of the procedure required by law and issue an order finding that Plaintiffs' claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT VI

Violation of 5 U.S.C § 706(2)(E)

(not supported by substantial evidence)

38. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as not supported by substantial evidence and issue an order finding that Plaintiffs'

claims are covered and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

VII. REQUEST FOR DECLARATORY JUDGMENT

39. It is appropriate to declare the rights and legal relations of both Plaintiffs regarding payment of the past and future monthly claims for Tumor Treatment Field Therapy by the Medicare program.

VIII. JURY DEMAND

40. PLAINTIFFS DEMAND A JURY TRIAL.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that this Court:

A. Enter a declaratory judgment:

- (1) Holding that the Secretary is precluded by principles of collateral from relitigating whether Tumor Treatment Field Therapy treatment for Plaintiffs is a covered benefit;
- (2) Holding that, in light of the prior decisions granting coverage, the denials at issue in this case are arbitrary and capricious;
- (3) Holding that TTFT is medically reasonable and necessary for each of the Plaintiffs and a covered Medicare benefit;

B. Enter an order directing the Secretary to cover the claims at issue in this case.

C. Enter a permanent injunction directing the Secretary to cover future monthly claims for Tumor Treatment Field Therapy made on behalf of the Plaintiffs.

D. Award attorneys' fees and costs to Plaintiffs as permitted by law.

E. Provide such further and other relief that this Court deems appropriate.

Dated: February 7, 2020

Respectfully submitted,

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